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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,194	12/03/2003	Robert B. Odell	P-4173C1C1	6906
26253 7590 03/27/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER STIGELL, THEODORE J				
ART UNIT 3763		PAPER NUMBER		
MAIL DATE 03/27/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,194

Applicant(s)

ODELL ET AL.

Examiner

THEODORE J. STIGELL

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The limitation of "the ratio of the inside diameter of said chamber to the diameter of said passageway being selected such that the fluid pressure in the flush solution injected through the passageway is less than 40 psi when a ten pound force is applied to the plunger rod" does not appear to be described in the specification. There is no description of a ratio between the chamber diameter and the passageway diameter. The applicant does not even appear to disclose preferable diameters of the passageway. One skilled in the art would not be able to determine why the ratio between these two diameters is important in reducing the pressure of a flush syringe.

Claims 1-13 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. In regard to claims 1 and 25, there does not appear to be an original disclosure of a ratio between the chamber diameter and the passageway diameter that will result in fluid pressure less than 40 psi when a ten pound force is applied to the plunger rod. In regard to claim 10, there is no disclosure of an "inside diameter" of "14.43 mm (0.568 inch)".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are deemed to be indefinite as the applicant is claiming an unrestricted range. The limitation of "said chamber having an inside diameter of at least 13.5 mm (0.53 inch)" essentially claims that any diameter above 13.5 mm for the chamber will be suitable for making the syringe. The unrestricted range renders the claims to be indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howe (5,242,405). Howe discloses a syringe (20) comprising a syringe barrel (21) having an elongated body and chamber, an open proximal end, a distal end (33) and a frusto-conically shaped tip (34) extending from the distal end having a tip passageway therethrough in fluid communication with the chamber, a rubber stopper (39) in fluid-tight engagement inside the barrel, an elongated plunger rod (40) defining a longitudinal axis and extending proximally from the stopper through the open end, and a flange (not numbered) at the proximal end, a tip cap (44) for sealing the passageway, and a flush solution (43) in the chamber, and the barrel includes measuring indicia (35a).

Howe does not specifically disclose the recited diameter or length of the chamber. Howe also does not disclose the limitation of "the ratio of the inside diameter of said chamber to the diameter of said passageway being selected such that the fluid pressure in the flush solution injected through the passageway is less than 40 psi when a ten pound force is applied to the plunger rod". These limitations are not being given patentable weight by the examiner.

In regard to the recited diameter, the examiner contends that the standard size of a syringe is larger than 13.5 mm and therefore if the syringe barrel of Howe is not inherently greater than 13.5 mm, it would certainly be obvious to modify the barrel to

this size. The examiner is relying on the applicant's admission in paragraph [0004] of the patent application publication that the standard size is greater than 13.5 mm.

In regard to the recited length, the examiner is interpreting this limitation to be an obvious modification as a mere change in the size and/or shape of the prior art device. The length of the syringe barrel does not appear to be involved in the reduced pressure of the flush solution as the applicant claims that it is the ratio between the chamber diameter and passageway diameter that results in a reduced pressure.

In regard to the ratio limitation, the examiner contends that there is no support for this limitation in the specification. Accordingly, this limitation is not being given patentable weight. One of ordinary skill in the art would find it obvious to modify the dimensions of the syringe barrel to adjust the pressure of the output fluid.

In regard to claims 25-27, Howe discloses the claimed invention except for multiple syringe barrels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include multiple syringes, since it has been held "...that duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)."

Response to Arguments

Applicant's arguments with respect to claims 1-13 and 25-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763